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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/491,892	07/14/95	HANSEN	E 218100

CUSHMAN DARBY AND CUSHMAN
1100 NEW YORK AVENUE NW
NINTH FLOOR
WASHINGTON DC 20005-3918

12M2/1009

RADIO, R EXAMINER	
ART UNIT	PAPER NUMBER

1209
DATE MAILED:

4
10/09/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/491,892

Applicant(s)

Hansen et al.

Examiner

Barbara Badio

Group Art Unit

1209



☒ Responsive to communication(s) filed on Jul 14, 1995

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are rejected as stated above because, it is improper to have a footnote in the claim section. The rejection can be overcome by (i) removal of the footnote since, the term was previously defined in the specification (pg. 1, lns 12-14) or (ii) incorporation of the term into claim 1.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

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person or subject to an obligation of assignment to the same person.

a. Claims 1-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Calverley et al. ('048) in view of Jolly et al. ('325).

Calverley et al. teach a generic group of vitamin D analogues and the compound calcipotriol (col. 9, fig. VI and table 2, compounds 54-55). The reference also teaches pharmaceutical compositions in a variety of formulations including creams, ointments or lotions containing 1-1000 ug/g of the compound(s) for topical treatment of dermatological disorders (col. 15, lns 55-68; col. 16, lns 1-58).

The instant invention differs from the reference by reciting a monohydrate of calcipotriol. Jolly et al. teach a monohydrate of $1\alpha,25$ -dehydroxy-cholecalciferol (see abstract). The reference also teaches that the hydrated form of $1\alpha,25$ -dehydroxy-cholecalciferol increases stability, is easily obtained in the pure form and can be perfectly crystallized (col. 1, lns 5-27; 47-53). Therefore, one having ordinary skill in the art at the time of the invention would have been motivated to make the monohydrate of calcipotriol taught by Calverley et al. with the reasonable expectation that the monohydrate would have the

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advantages taught by Jolly et al. (ie. it would be more stable, easily crystallized and, thus, suitable for pharmaceutical use).

Telephone Inquiry Contacts

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

BB

October 7, 1996

**KIMBERLY J. PRIOR
PRIMARY EXAMINER
GROUP 1200**